

REMARKS**Status of the Claims**

Claims 8, 9 and 18-23 are still pending.

35 U.S.C. 103(a) rejection

Claims 8, 9 and 18-21 were rejected as being obvious over Caserio et al. (U.S. Patent 4,664,910 - "Caserio") in view of Tisdale et al. (U.S. Patent 6,103,246 - "Tisdale").

Claims 22 and 23 were rejected as being obvious over Caserio et al., *id.* and Tisdale et al., *id.*, further in view of Pitrof et al. (U.S. Patent 5,376,646).

Reply to Examiner's Rejection and "Response to Arguments"

- (1) **Encapsulated bile acid/salt preparation are unobvious over Caserio in view of Tisdale (Claims 8, 9, 18 and 21)**

Standard of Review for Obviousness

MPEP 2141 states:

"Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C 103...the four factual inquiries enunciated therein as background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the art; and
- (D) Evaluating evidence of secondary considerations.....

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined

Hodash v. Block Drug Co., Inc. 786 F.2d 1136, 1143, n.5, 229 USPQ 187 n.5 (Fed. Cir. 1986)." (emphasis added).

With respect to the rejections of the dependent claims, MPEP 2143.03 states that "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." (see also *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

With respect to whether the evidence supports a *prima facie* holding obviousness, the standard is a "preponderance of evidence", i.e. more likely than not (see MPEP 2142).

(a) Statement of facts about teachings of Caserio and Tisdale

Although the examiner's characterization about the Caserio and Tisdale references are substantially correct (which includes the acknowledgment that Caserio does not teach encapsulated forms of their compositions), nonetheless there are some key elements which are missing from the "as a whole" consideration of the references which must be adhered to when applying 35 U.S.C. § 103.

Regardless of how one elects to characterize what compounds Caserio's composition encompasses, it is undisputed that Caserio directs one of ordinary skill in the art to produce compositions which can remove sebum [an oil secretion of the sebaceous glands] and/or perspiration (see e.g. Abstract).

Tisdale is relied upon by the examiner for their teachings on the use of encapsulated forms, specifically the use of liposomes (see col. 2, lines 38-59 and col. 3, lines 23-24). However, the very next section of col. 2 in Tisdale appears to discredit the use of liposomes (see col. 2, lines 60-67):

"Even liposomes have proven only partially effective in providing adequate penetrability, as desired for many cosmetics applications. Further, the addition of liposomes to cosmetics preparations can significantly increase the cost of the preparations. Clearly, it would be both technologically and commercially advantageous to use some other or additional penetrating composition in cosmetics to achieve the desired penetration results." (emphasis added)

Moreover, the compositions of Tisdale are directed toward the enhancing the delivery of an oil to the skin, e.g. emu oil (see Abstract).

(b) No motivation to combine the references as indicated by the examiner

Looking within the entire contents of the Caserio and Tisdale references, it appears that the necessary elements of the applicants invention could be extracted. However, determination of obviousness does not reside in a mere scavenger hunt to collect the necessary elements. As stated in *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998):

"As this court has stated, '*virtually all [inventions] are combinations of old elements...* Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat patentability of the claimed invention. *Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'* *Sensotronics, Inc. v. Aerasonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996)." *Rouffet*, 149 F.3d at 1357, 47 USPQ2d at 1457.

As stated in the applicants' previous response, the ruling on obviousness in *In re Fine* closely adheres to the position maintained by the applicants and is reproduced in part below:

"Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it 'cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And 'teachings of references can be combined only if there is some suggestion or incentive to do so.' *Id.* Here the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination....

It is essential that 'the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made...to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.' *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." see *In re Fine*, 5 USPQ2d 1596, 1599, 1600 (Fed. Cir. 1988).

Placing one of ordinary skill in art back to the date this application was filed and placing the Caserio and Tisdale references before him without the benefit of the applicants claims to act as a guide, there is no reason to believe the skilled artisan would have discovered the applicants' invention without undue experimentation.

Moreover, the reason presented by the examiner as motivation ("the expectation of successfully achieving a cosmetic composition with enhanced skin penetration and time-released action") for modifying Caserio with Tisdale is unconvincing on at least three separate levels:

- (i) There is no reason one of ordinary skill in the art would seek to modify Caserio's composition designed to *remove* oil [sebum] by using the teachings of Tisdale's composition which is

designed to **deliver** oil [emu oil].

- (ii) There is no reason why one of ordinary skill in the art should ignore the remainder of the teachings of Tisdale as a whole and focus entirely on their teachings of the use of liposomes, i.e. no reason why picking and choosing should be allowed.
- (iii) Even if picking and choosing were allowed, the Tisdale reference itself is less than certain as to whether liposomes are an appropriate carrier for their own invention much less that of Caserio's.

(c) No showing that Caserio teaches the limitation of claim 21

The examiner acknowledges that Caserio lacks a specific teaching for using antioxidants and can only point to Example 6 for any evidence suggesting the use of an antioxidant. However, even in this example, it is unclear that this example meets the limitations of the applicants claims as Example 6 recites a content of "pigment and antioxidant" being 1.03% (see col. 8).

Given the lack of guidance about the use of antioxidant in the Caserio reference, there is no reason to believe that Caserio intended the amount of antioxidant to be 1% or greater of the 1.03% represented by the "pigment and antioxidant" (i.e. if one of ordinary skill in the art was asked for an interpretation of the amount of antioxidant based on the teachings of Caserio without any other guidance, a reasonable interpretation would be that Caserio teaches equal amounts of both pigment and antioxidant, i.e. 0.515% which is outside the range claimed by the applicants in claim 21.

Such that it could be argued that the 0.515% or amount less than 1% for the amount of antioxidant could be optimized by one of ordinary skill in the art (see MPEP 2144.05 II. A.), this is only applicable if the prior art recognizes this as a results effective variable which Caserio clearly does not. (see MPEP 2144.05 section II (Optimization of Ranges) states that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).")

For the foregoing reasons, it is believed that claims 8, 9 and 18-21 are unobvious over the prior art.

- (2) Method of strengthening claims are unobvious over the Caserio in view of Tisdale (Claims 19 and 20)

On page 3, lines 15-19 of the examiner's office action, it was written (Statement #1): "Any properties exhibited by or benefits provided the compositions are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicants disclose and/or claims are necessarily present." (emphasis added)

On page 5, lines 16-19 of the examiner's office action, it was written (Statement #2): "The fact that all the claims of in (sic) *In re Spada* were composition claims are viewed as irrelevant in this case because that does not change the fact that the Caserio bile acids perform the same function as applicants are claiming in this case."

(a) Examiner's *In re Spada* analysis is factually and legally incorrect

MPEP 2144.04 states that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." However, Statements #1 and #2 suggest that the *In re Spada* decision has not been read in its entirety by the examiner and as such a copy of the decision is attached to this office action and is further discussed below.

Statements #1 and #2 above represent a mischaracterization of the *In re Spada* decision. The misappropriated passage from *Spada* which the examiner presumably relied upon reads as follows:

"Products of identical chemical composition cannot have mutually exclusive properties. See *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) (a chemical compound and its properties are inseparable)." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)(emphasis added).

The key distinction between Statement #1 and that of *Spada* is that it is a chemical compound **NOT composition** whose properties are inseparable. The properties of chemical compositions are inseparable only for the unique situation where the compositions are identical and the *Spada* decision represents a natural progression from the *Papesch* decision (i.e. a sample of Compound X would be expected to have the same properties as another sample of Compound X and therefore a sample composition comprising Compounds X, Y and Z would be expected to have the same properties as

another sample composition also comprising Compounds X, Y and Z). This is consistent with the issues of anticipation being decided in *Spada* (see the three headnotes on the first page of *Spada*).

However, this is not the case here. The rejections made are based on obviousness and it has been acknowledged by the examiner that there is at least one difference between the applicants' claimed invention and Caserio, i.e. Caserio does not teach encapsulated forms of their invention. Therefore, the composition of Caserio and the composition of the applicants' invention are not identical and therefore do not necessarily have the same properties.

- (b) When compositions are not identical, burden resides with the examiner to show that applicants' composition and composition of the prior art inherently have the same properties

The properties of the composition were asserted to be inherently the same by the examiner in Statement #1 above. However, as explained in (a) above, the mere presence of one common compound in two different compositions is insufficient to establish that both compositions have the same properties.

MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof) states "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)....To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

At this point, there is no evidence of record which supports the examiner's assertion of inherency.

- (c) No evidence that Caserio teaches that bile salts alone are effective for strengthening the barrier of the skin as in the applicants' invention

If additional evidence need be presented to establish inherency, the applicants also direct the examiner's attention to the fact that there is no teaching in Caserio which establishes that the use of

cholic acid (a specific bile acid) alone produces the effect of strengthening the barrier of the skin. The passage referred to by the examiner in Caserio reference (col. 5, lines 1-7) teaches removal of grease and moisture and only shows the skin "will remain in a healthy pliable [easily bent] state" which at best shows only a neutral effect on the skin and is not indicative of a positive effect on the skin, i.e. strengthening the barrier of the skin.

Moreover, it cannot even be adduced that cholic acid *alone* is effective for reducing grease and/or moisture as is stated in col. 5, lines 1-7, i.e. the properties of cholic acid are never discussed in a vacuum but within the context of being combined with an absorbent substance.

(d) The Tisdale reference does not remedy the deficiencies of the Caserio reference

The impropriety of combining Tisdale with Caserio is addressed above. However, even if it were conceded that it was appropriate to combine Tisdale with Caserio, the substance of the Tisdale reference relied upon was directed toward the difference in encapsulation and does not remedy the deficiencies of the Caserio reference with respect to the method of strengthening the barrier of the skin.

For the foregoing reasons, it is believed that claims 19 and 20 are unobvious over the prior art.

(3) **Encapsulated bile acid/salt preparation are unobvious over Caserio in view of Tisdale and Pitrof (Claims 22 and 23)**

Should the rejection of claims 8, 9 and 18-21 be withdrawn, then it is believed that the rejection of claims 22 and 23 would also be withdrawn.

As stated in the previous response, given the lack of direction with respect to the use of an antioxidant, there is no reason why one of ordinary skill in the art would elect to use vitamin E from the teaching of Pitrof in the composition of Caserio and Tisdale. It is has long been held that when presenting a limitless set of choices is not indicia of obviousness:

"...the board said, referring to the appellant's ingredients, 'It should be noted that an infinite number of combinations is possible.' Accepting that as an approximation to the truth, we fail to see the obviousness in devising appellant's....[invention] as claimed." *In re Rice*, 481 F.2d 1316, 1319, 178 USPQ 478, 480 (CCPA 1973).

Moreover, Pitrof also suffers from the same weakness as the Tisdale reference, i.e. it is an oil

[lipid] containing composition, and being used to modify Caserio's composition which is directed toward removing oil.

For the foregoing reasons, it is believed that claims 22 and 23 are unobvious over the prior art.

Closing

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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Attachment: Copy of *In re Spada* (4 pages)

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (15 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 24 March 2004

By: Agata Glinska
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